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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/529,984	03/31/2005	Emadeldin M. Hassan	B4700-597US	6260

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EXAMINER	
ELLIS, SUEZU Y	

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
04/24/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/529,984	HASSAN ET AL.	
	Examiner	Art Unit	
	Suezu Ellis	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 April 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16 and 18-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-16 and 18-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *9/16/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Priority

If applicant desires to claim the benefit of a prior-filed application under 35 U.S.C. 119(e), a specific reference to the prior-filed application in compliance with 37 CFR 1.78(a) must be included in the first sentence(s) of the specification following the title or in an application data sheet. For benefit claims under 35 U.S.C. 120, 121 or 365(c), the reference must include the relationship (i.e., continuation, divisional, or continuation-in-part) of the applications.

If the instant application is a utility or plant application filed under 35 U.S.C. 111(a) on or after November 29, 2000, the specific reference must be submitted during the pendency of the application and within the later of four months from the actual filing date of the application or sixteen months from the filing date of the prior application. If the application is a utility or plant application which entered the national stage from an international application filed on or after November 29, 2000, after compliance with 35 U.S.C. 371, the specific reference must be submitted during the pendency of the application and within the later of four months from the date on which the national stage commenced under 35 U.S.C. 371(b) or (f) or sixteen months from the filing date of the prior application. See 37 CFR 1.78(a)(2)(ii) and (a)(5)(ii). This time period is not extendable and a failure to submit the reference required by 35 U.S.C. 119(e) and/or 120, where applicable, within this time period is considered a waiver of any benefit of such prior application(s) under 35 U.S.C. 119(e), 120, 121 and 365(c). A benefit claim

filed after the required time period may be accepted if it is accompanied by a grantable petition to accept an unintentionally delayed benefit claim under 35 U.S.C. 119(e), 120, 121 and 365(c). The petition must be accompanied by (1) the reference required by 35 U.S.C. 120 or 119(e) and 37 CFR 1.78(a)(2) or (a)(5) to the prior application (unless previously submitted), (2) a surcharge under 37 CFR 1.17(t), and (3) a statement that the entire delay between the date the claim was due under 37 CFR 1.78(a)(2) or (a)(5) and the date the claim was filed was unintentional. The Director may require additional information where there is a question whether the delay was unintentional. The petition should be addressed to: Mail Stop Petition, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450.

If the reference to the prior application was previously submitted within the time period set forth in 37 CFR 1.78(a), but not in the first sentence(s) of the specification or an application data sheet (ADS) as required by 37 CFR 1.78(a) (e.g., if the reference was submitted in an oath or declaration or the application transmittal letter), and the information concerning the benefit claim was recognized by the Office as shown by its inclusion on the first filing receipt, the petition under 37 CFR 1.78(a) and the surcharge under 37 CFR 1.17(t) are not required. Applicant is still required to submit the reference in compliance with 37 CFR 1.78(a) by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

Information Disclosure Statement

The information disclosure statement (IDS) submitted on September 16, 2005 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5-11 and 13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okajima (US 4,138,013) in view of Hirai et al. (US 3,826,666).

With respect to claims 1-3, 5-11, and 13 Okajima discloses a gel mass composition comprising a film-forming, water-soluble polymer (gelatin or hydroxypropyl methylcellulose), an acid-insoluble polymer (cellulose acetate phthalate or hydroxypropyl methylcellulose phthalate), an alkaline aqueous solvent (dilute aqueous solution of ammonium hydroxide), and optionally a plasticizer (polyethylene glycol) and optionally a coloring agent (col. 3, lines 54-64; col. 4, lines 31-38). Okajima further discloses the final pH of the gel mass is less than or equal to about 9 pH units (col. 4, line 10). Okijima illustrates in Example 2 the ratio of acid-insoluble polymer to film-forming polymer being 50:50, however fails to expressly disclose the ratio being from about 30:70 to about 45:55 by weight. Hirai et al. discloses the ratio of acid-insoluble

polymer to film-forming polymer is in a range of 1:1.5 to 1:4 (col. 3, lines 46-48), and therefore can be within the claimed range (1:1.5). It would have been obvious to one of ordinary skill in the art to modify the ratio of the acid-insoluble polymer to film-forming polymer in order to provide a capsule with the property of being an insoluble capsule when in the stomach acid but also to rapidly dissolve when it comes in contact with the alkaline secretions of the intestine, as taught by Hirai (col. 3, lines 36-45). Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Okajima in view of Hirai et al. and further in view of the teachings of Shank (US 4,500,453).

With respect to claim 4, the modified Okajima addresses all the limitations of claims 1-3, however fails to expressly disclose the gelatin is extracted from animal bones or skins and has about 100-250 blooms. Shank teaches it is well known in the art that gelatin used is from animal bones (col. 1, lines 22-26). Shank further teaches it is well know in the art for hard enteric capsules to be made with gelatin having about 100-250 blooms (col. 1, line 67 - col. 2, line 21). It would have been obvious design choice to one of ordinary skill in the art to utilize animal gelatin with blooms between 100-250 blooms in order to create a hard capsule.

Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Okajima in view of Hirai et al. and further in view of Itoh et al. (US 5,194,464).

With respect to claim 12, the modified the modified Okajima addresses all the limitations of claim 1, however fails to expressly disclose the alkaline aqueous solution being a hydroalcoholic solution. Itoh et al. teaches using a mixture of ethanol and water (hydroalcoholic solution) as a solvent to dissolve hydroxypropyl methyl cellulose phthalate (col. 3, lines 26-30). It would have been obvious to one of ordinary skill in the art to modify the solution used in order to provide a suitable solvent for dissolving the acid-insoluble polymer.

Claims 14-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okajima in view of Hirai et al. and further in view of Matthews et al. (US 4,816,259)

With respect to claims 14-16, the modified Okajima addresses all the limitations of claim 1, however fails to expressly disclose the gel mass composition used in producing an enteric soft capsule shell. However, the modified Okajima does disclose the claimed structural feature of the gel mass composition, and therefore is considered to be capable of producing an enteric soft capsule shell. The modified Okajima also fails to expressly disclose the moisture content being about 8%. Matthews et al. teaches it is well known in the art for enteric soft capsules to have a moisture content of about 8-10% (col. 2, line 18; col. 4, lines 19-20). It would have been obvious to one of ordinary skill in the art to modify the moisture content in order to create the desired wall thickness, as taught by Okajima (col. 4, lines 15-20).

Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Okajima in view of Hirai et al. and further in view of Venkateswara et al. (WO 01/24780).

With respect to claims 18, the modified the modified Okajima addresses all the limitations of claim 1, and further discloses the inclusion of a plasticizer (col. 4, lines 31-38). However, the modified Okajima fails to expressly disclose the ratio of plasticizer to film-forming water-soluble polymer being from 1:9 to 1:1. Venkateswara et al. discloses in the examples an enteric soft capsule having a plasticizer and a film-forming water-soluble polymer within the claimed range (Examples). It would have been obvious to one of ordinary skill in the art to modify the amount of plasticizer as desired in order to prevent the formation of pores and cracks that would permit penetration of the gastric fluids. Further, it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or working ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.

With respect to claim 19, the modified the modified Okajima addresses all the limitations of claim 1, however fails to expressly disclose the ratio of plasticizer to film-forming water-soluble polymer being 1:3. However, it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980)

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Venkateswara et al. in view of Hirai et al. and further in view of Matthews et al.

With respect to claim 20, Venkateswara et al. discloses an enteric soft capsule shell formed from a gel mass composition comprising a film-forming, water-soluble polymer (gelatin), an acid-insoluble polymer (hydroxypropyl methylcellulose phthalate), and an alkaline aqueous solvent (ammonia solution) (pg. 5, lines 21-40; Examples). Venkateswara et al. discloses the acid-insoluble polymer can be 40% by weight of the dried shell (pg. 5, lines 25-27), therefore is considered to be about 30:70 (42%). Venkateswara et al. fails to expressly disclose the final pH of the gel mass is less than or equal to about 9 pH units. Hirai et al. further discloses the final pH of the gel mass is less than or equal to about 9 pH units (col. 3, lines 12-13). It would have been obvious to one of ordinary skill in the art to modify the final pH of the gel mass in order to prevent the alteration of the gelatin (col. 3, lines 6-8). The modified Venkateswara et al. also fails to expressly disclose the moisture content of the capsule shell being 8-10%. Matthews et al. teaches it is well known for enteric soft capsule shells to have a moisture content of 8-10% (col. 2, line 18; col. 4, lines 18-20). It would have been obvious to one of ordinary skill in the art to modify the moisture content of the shell in order to modify the moisture content in order to create the desired wall thickness, as taught by Hirai et al. (col. 3, lines 51-58).

Telephone/Fax Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suezu Ellis whose telephone number is (571) 272-2868. The examiner can normally be reached on 8:30am-5pm (Monday-Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharon Kennedy can be reached on (571) 272-4948. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

SE

/Sharon E. Kennedy/
Primary Examiner, Art Unit 1615